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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER
BORIN, M

ART UNIT	PAPER NUMBER
1631	13

DATE MAILED: 07/25/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/215,095

Applicant(s)

Becker et al

Examiner

M. Borin

Group Art Unit
1631



☒ Responsive to communication(s) filed on Jun 30, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-65 is/are pending in the application.

Of the above, claim(s) 4, 12-22, 26, and 34-56 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-3, 5-11, 23-25, 27-33, and 57-65 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

The request filed on 06/30/2000 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/215095 is acceptable and a CPA has been established. An action on the CPA follows.

Status of the claims

1. Claims 1-65 are pending.

As reflected in the previous Office action, applicant elected, without traverse, Group II, claims 1,2,6-11 (all in part), claims 3,5, claims 23, 24, 28-33 (all in part), claim 25,27, drawn to granules combining a protein, a disaccharide, and a polysaccharide. Newly submitted claims 57-65 are also included into the elected Group. Claims 4,12-22,26,34-56 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected groups. Cancellation of claims 4,12-22,26,34-56, and amendment of claims 1,2,6-11, 23, 24, 28-33 to read on elected invention are requested.

Claim Rejections - 35 USC § 102 and 103.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C.102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States..

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1-3,5-11,23-25,27-33, 57-65 are rejected under 35 U.S.C. 102(b) as anticipated by Kiesser et al. (US Patent 5,739,091)

Kiesser

Kiesser et al. teach enzymic granules. The granules comprise enzyme or enzyme mixture, sugars, such as glucose, and a filler, such as cellulose. See column 1, lines 31-39, 60-67, column 2, line 66 to col. 3, line 4. The granules may further comprise binders, such as polyethyleneglycol. See col. 2, lines 16-24. The granules may be covered with a protective coating (col.4, lines 5-11). The

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coating can contain sugars (col. 4, lines 8-10) or polyethyleneglycol (col.4, line 46). The granules may be prepared by layering the enzyme around dry pre-mix. See col. 4, lines 21-24.

It is the Examiners position that all the elements of Applicant's invention with respect to the specified claims are instantly disclosed by the teaching of the reference cited above.

4. Claims 1-3, 5,6, 23-25,27,28, 57-65 are rejected under 35 U.S.C. 102(b) as anticipated by Scott (EP 272923).

Scott

Scott teaches granules including enzyme(glucose oxidase), sugar (glucose), low molecular weight polysaccharide (e.g., cellulose), and optionally synthetic polymer (e.g., polyethylene glycol). See abstract, p.5, lines 7-13,; p. 2, lines 43-54.

It is the Examiners position that all the elements of Applicant's invention with respect to the specified claims are instantly disclosed by the teaching of the reference cited above.

5. Claims 1, 7-11, 23, 29-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scott et al. The reference is used as applied to claims 1-3, 5,6, 23-25,27,28, 57-65 in the preceeding paragraph. The reference does not teach forming a granule over a seed particle and the presence of a coating layer over the granule. If there are any differences between Applicant's claimed methods and that of the prior art, the differences would be appear minor in nature. Although Scott does not not teach protein core layered over a seed particle and coating the particle, it would be conventional

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and within the skill of the art to prepare such granule because the techniques of using a seed particle for the intended purpose of forming a granule and coating the granule to protect its content are well known in the pharmaceutical art, and are within the skill in the art to which this invention pertains.

6. Claims 1-3, 5,6-11,23-25,27-33, 57-65 are rejected under 35 U.S.C.103(a) as obvious over Martussen (EP 304332).

Martussen

Martussen teaches enzyme granules comprising an enzyme core surrounded by a coating comprising cellulose or artificial binders. The granule further comprises a binder, such as polyvinyl pyrrolidone, cellulose derivatives, etc., and a granulating agent, such as polyglycols. See abstract, pages 2-3. The referenced granule does not contain sugar and polysaccharide. However, addition of such ingredients would be *prima facie* obvious when the enzyme granulates are to be used as nutrient additives, because the reference teaches that in such cases the core could contain sugar, or starch, or protein. See p. 2, lines 32-34.

Further, in regard to claims 7,9,29,31, if there are any differences between Applicant's claimed methods and that of the prior art, the differences would be appear minor in nature. Although the prior art does not not teach protein core layered over a seed particle, it would be conventional and within the skill of the art to prepare such granule because the techniques of using a seed particle for

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the intended purpose of forming a granule is well known in the pharmaceutical art, and are within the skill in the art to which this invention pertains.

Prior art made of record

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: EP 501375, EP 336231, US 5,814,501, WO 97/23606.

Conclusion.

8. No claims are allowed.
9. This is a CPA of applicant's earlier Application No. 09/215095. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be

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calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

July 21, 2000

mlb



MICHAEL BORIN, F.I.D.
PATENT EXAMINER